

U.S. Department of Health and Human Services
Food and Drug AdministrationFor use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

MEDWATCH

FORM FDA 3500A (10/05)

Page ____ of ____

Mfr Report #

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or _____ Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight ____ lbs or ____ kgs
-----------------------	--	--	---

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
(Check all that apply)

<input type="checkbox"/> Death: _____ (mm/dd/yyyy)	<input type="checkbox"/> Disability or Permanent Damage
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital Anomaly/Birth Defect
<input type="checkbox"/> Hospitalization - initial or prolonged	<input type="checkbox"/> Other Serious (Important Medical Events)
<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)	

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
-------------------------------	-------------------------------------

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)	
#1 _____	
#2 _____	
2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1 _____	#1 _____
#2 _____	#2 _____
4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1 _____	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2 _____	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot #	7. Exp. Date
#1 _____	#1 _____
#2 _____	#2 _____
9. NDC# or Unique ID	
#1 _____	
#2 _____	
8. Event Reappeared After Reintroduction?	
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)	

D. SUSPECT MEDICAL DEVICE

1. Brand Name		
2. Common Device Name		
3. Manufacturer Name, City and State		
4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Health Professional
Serial #	Other #	<input type="checkbox"/> Lay User/Patient
6. If Implanted, Give Date (mm/dd/yyyy)		<input type="checkbox"/> Other: _____
7. If Explanted, Give Date (mm/dd/yyyy)		
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor		
10. Device Available for Evaluation? (Do not send to FDA)		
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: _____ (mm/dd/yyyy)		
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)		

E. INITIAL REPORTER

1. Name and Address	Phone #
2. Health Professional?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Occupation	4. Initial Reporter Also Sent Report to FDA
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

MEDWATCH

FORM FDA 3500A (10/05) (continued)

Page ____ of ____

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)		
1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. UF/Importer Report Number
3. User Facility or Importer Name/Address		
4. Contact Person		5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)	7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____	8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device	10. Event Problem Codes (Refer to coding manual) Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____	
11. Report Sent to FDA? <input type="checkbox"/> Yes _____ (mm/dd/yyyy) <input type="checkbox"/> No	12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other: _____ (Specify)	
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes _____ (mm/dd/yyyy) <input type="checkbox"/> No		
14. Manufacturer Name/Address		

G. ALL MANUFACTURERS		
1. Contact Office - Name/Address (and Manufacturing Site for Devices)		2. Phone Number
4. Date Received by Manufacturer (mm/dd/yyyy)		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: _____
6. If IND, Give Protocol #	5. (A)NDA # _____ IND # _____ STN # _____ PMA/ 510(k) # _____ Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____		
9. Manufacturer Report Number	8. Adverse Event Term(s)	

H. DEVICE MANUFACTURERS ONLY	
1. Type of Reportable Event <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction <input type="checkbox"/> Other: _____	2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation
3. Device Evaluated by Manufacturer? <input type="checkbox"/> Not Returned to Manufacturer <input type="checkbox"/> Yes <input type="checkbox"/> Evaluation Summary Attached <input type="checkbox"/> No (Attach page to explain why not) or provide code: _____	4. Device Manufacture Date (mm/yyyy) 5. Labeled for Single Use? <input type="checkbox"/> Yes <input type="checkbox"/> No
6. Evaluation Codes (Refer to coding manual) Method _____ - _____ - _____ - _____ Results _____ - _____ - _____ - _____ Conclusions _____ - _____ - _____ - _____	
7. If Remedial Action Initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Notification <input type="checkbox"/> Repair <input type="checkbox"/> Inspection <input type="checkbox"/> Replace <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Relabeling <input type="checkbox"/> Modification/ Adjustment <input type="checkbox"/> Other: _____	8. Usage of Device <input type="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number: _____
10. <input type="checkbox"/> Additional Manufacturer Narrative and / or 11. <input type="checkbox"/> Corrected Data	

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.